



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,335	10/26/2007	Kenji Yokoyama	201487/1190	9427

50828 7590 03/28/2011
DAVID S. RESNICK
NIXON PEABODY LLP
100 SUMMER STREET
BOSTON, MA 02110-2131

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
----------	--------------

1759

MAIL DATE	DELIVERY MODE
-----------	---------------

03/28/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,335	Applicant(s) YOKOYAMA ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/23/2007 (preliminary amndt.).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-15 is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/04/2009 and 11/15/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burns et al. US 2003/0116437 A1 (“Burns”).

Addressing claim 19, Burns discloses a method for separating biomolecules (see paragraph [0013]), comprising the steps of:

a) adding a biomolecule to be analyzed (paragraph [0091]) to a microchannel chip (see paragraphs [0090] and [0076]-[0078]) made by laminating a cover material to a channel-side surface of a substrate on which a channel has been formed (see paragraph [0076]. The Examiner construes the bonding of the etched glass channel network to the silicon/quartz substrate to be a type of laminating), and coating a surface of the channel on the substrate surface with a polymer membrane (paragraph [0090]); and

b) applying a separation pressure to a separating medium (implied since “The migrating bands were detected ...” See paragraph [0091]).

Addressing claim 20, for the additional limitation of this claim see paragraph [0090]. Note that is within a section entitled "Example 1 – Electrophoresis Procedure". Also see the abstract and paragraphs [080], [0081], and [0013].

Addressing claim 21, for the additional limitation of this claim see paragraph [0037]. Although not labeled as such, the electrophoresis channels have capillary dimensions (microscale).

Addressing claim 22, for the additional limitation of this claim see paragraph [0013]. Note, "The electrophoresis includes, but are not limited to, the electrophoresis of nucleic acids, *proteins*, etc. [emphasis added]"

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1759

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dantsker et al. US 6,499,499 B2 ("Dantsker").

Danskter meets all of the limitations of these claims. See in Dantsker col. 13:09-43 and col. 13:65 – col. 14:09.

With regard to claim 16, as a first matter, whether the cover material is laminated to a channel-side surface of a substrate on which a channel has been formed, after a part or entire surface of the channel surface is coated with a polymer membrane, as implicitly claimed, or before a part or entire surface of the channel surface is coated with a polymer membrane, as disclosed by Dantsker, is a product-by-product limitation that, barring a contrary showing does not materially affect the resulting microchannel chip. In other words, the microchannel chip formed by Dantsker is presumed the same as would result if made as claimed. See MPEP 2113.

With regard to claim 17, since in Dantsker the channel is filled with pre-polymer membrane forming solution, pre-polymer membrane forming solution will contact the substrate-side surface of the cover. So when the microchannel chip (150) is exposed to the curing light (205) over the top of the microchannel chip (Figure 7C) a polymer membrane will inherently also be formed on the substrate-side surface of the cover material after the curing step.

With regard to claim 18, since in Dantsker each channel is symmetrical with respect to the top portion and the bottom portion, a mask (190) is placed over the top of a selected channel portion of the microchannel chip, and the curing light is exposed directly over this mask (Figure 7C), one would expect the shape of the polymer membrane formed on the an area on the substrate-side surface of the cover material to be at least partially, if not identical in shape to the polymer membrane formed on the surface of the channel on the substrate.

7. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns in view of Chow et al. US 5,989,402 ("Chow")

Addressing claim 23, Burns discloses an apparatus for electrophoretic analysis (see paragraph [0013]) comprising the following components:

a) a microchannel chip (see paragraphs [0090] and [0076]-[0078]) made by laminating a cover material to a channel- side surface of a substrate on which a channel has been formed (see paragraph [0076]. The Examiner construes the bonding of the etched glass channel network to the silicon/quartz substrate to be a type of laminating), and coating a surface of the channel on the substrate surface with a polymer membrane (paragraph [0090]), and

b) electrodes used to apply a voltage to the microchannel chip retained by the support (see paragraphs [0086] and [0087] – "V. Design of Electrodes". Also see paragraphs [0028] and [0029].).

Burns does not mention using a support used to retain the microchannel chip, although this is arguably implied since Burns discloses the apparatus as a module to be integrated with an electronic detector and presumably a power supply for the electrophoresis electrodes. See paragraphs [0079]-[0081].

Chow discloses a support for retaining an electrophoresis microchannel chip. See the abstract, Figures 1 and 2A, and col. 07:23-30.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use a support for retaining an electrophoresis microchannel chip as taught

Art Unit: 1759

by Chow in the apparatus of Burns because as taught by Chow, 'These improved interfaces provide microfluidic systems that are easier to use, e.g., "user friendly," are more readily automatable, and as a result, have higher throughputs than previously described analytical systems.' See Chow col. 01:57-67. In this regard it should be noted that the microchannel chip is substantially planar and already has holes in the top surface to receive electrical connections or fluids (see paragraph [0078]), so only minor shape or design changes would be required to configure the support of Chow (e.g., Figure 2A) to retain the microchannel chip of Chow.

Addressing claim 24, although Burns as modified by Chow does not specifically mention using a photoresist-mask as the mask it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because the mask is to block out ultraviolet illumination. See Burns paragraph [0090], for example.

Allowable Subject Matter

8. Claims 1-15 are allowed.

9. The following is a statement of reasons for the indication of allowable subject matter:

a) the combination of limitations in claim 1 requires the step of “forming a polymer membrane on the exposed surface of the substrate.”

Li et al. WO 01/26812 A1 (“Li”) meets all of the limitations of Applicant’s claim 1 except, though, that Li forms metal electrodes for electrophoretic purposes on the exposed surface of the substrate, not a polymer membrane. See in Li the abstract; page 9, lines 09-20; and page 13, lines 12-18.

Bohn et al. US 7,220,435 B2 (“Bohn”) meets all of the limitations of Applicant’s claim 1 except, though, that Bohn forms “... a desired pattern of channels and holes into the solid membrane ...” That is, instead of forming a polymer membrane on the exposed surface of the substrate Bohn places an already existing membrane onto the substrate and forms more channels and holes into it. See col. 07:20 – col. 08:07 and Figures 5A-C.

In Dantsker and Karp et al. US 7,010,964 B2 (“Karp”), in contrast to the claimed invention, a cover material is laminated onto the substrate surface on which a channel has been formed, the channel network is filled with pre-polymer mixture, under pressure, with a syringe, for example, then the top of the microchannel chip is shielded so that pre-polymer mixture in only selected exposed channel regions can be cured into polymer membranes. See in

Dantsker col. 13:09-43 and col. 13:65 – col. 14:09, and in Karp col. 11:32 – col. 12:46.

In Burns et al. US 2003/0116437 A1 (“Burns”), in contrast to the claimed invention, a cover material is laminated onto the substrate surface on which a channel has been formed, the channel network is filled with pre-polymer mixture, apparently by wicking (capillarity), then the top of the microchannel chip is shielded so that pre-polymer mixture in only a selected exposed channel region can be cured into a polymer membrane. See Figures 1A-D; paragraph [0090]; paragraph [0076], first paragraph; paragraph [0078], first sentence; paragraph [0084], last sentence; and paragraph [0085].

In Yang et al. 6,841,193 B1 (“Yang”), in contrast to the claimed invention, a cover material is laminated onto the substrate surface on which a channel has been formed, the channel network is filled with pre-polymer mixture, apparently by capillarity or vacuum pressure, then the top of the microchannel chip is shielded so that pre-polymer mixture in only a selected exposed channel region can be cured into a polymer membrane. See Figure 1, col. 12:09-30, col. 15:59 – col. 16:20, col. 21:60 – col. 22:06, col. 24:01-16, col. 34:20-38, and col. 36:46-50.

b) Claims 2-15 depend directly or indirectly from allowable claim 1.

c) the International Search Report for International application no.

PCT/JP2005/003604 lists only a single document, JP 2001-252896 A, which it categorized as an "A" reference.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ALEXA NECKEL can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1759
March 24, 2011